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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,174	10/12/2000	Hilary Koprowski	JEFF-KOPOI.P	2234

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EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/11/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,174

Applicant(s)

KOPROWSKI ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I, claims 1-4, without traverse is acknowledged. Claims 1-16 are pending. Claims 5-16 are withdrawn from consideration being drawn to non-elected inventions. Claims 1-4 are examined on the merits.

Drawings

2. The drawings are objected to by the Draftsperson, see Form PTO 948. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites improper Markush language. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman *et al.* (U.S. Patent 4,956,286) in view of Ma *et al.* (*Eur. J. Immunol.* 1994 24 :131-138) and Lomonosoff *et al.* (U.S. Patent 5,874,087). The claims are drawn to a method for producing a full-length antibody in a host plant (dicotyledon or monocotyledon) using a virus comprising 1) constructing a first recombinant viral vector encoding heavy chain, 2) constructing a second recombinant viral vector encoding light chain, 3) infecting the host plant with both recombinant vectors to result in systemic infection and 4) expressing heavy and light chains in assembled form into full-length antibodies. The full-length antibody can be monoclonal, and can be directed against several disease-related antigens.

Goodman *et al.* disclose constructs for expression of physiologically active mammalian proteins in plant cells under cultivation, see abstract. Antigens of interest include immunoglobulins with the structural genes coding for the light and heavy chains and desirably assembly occurring in the plant cell. The antigens can be associated with viral pathogens such as surface antigens of hepatitis B virus, see column 3, lines 11-36. The DNA construct can be introduced into the plant cells (monocots or dicots) by viral infection, see column 4, lines 43-64. The infected plant cells are cultivated to express the protein of interest, and then the protein is harvested. Goodman *et al.* differs from the claimed invention because the production of monoclonal antibodies and the infection of plants (as opposed to plant cells) are not taught.

Ma *et al.* disclose the assembly of monoclonal antibodies in transgenic tobacco plants. Genes encoding heavy and light chains were ligated into plant expression vectors. The plants

expressing heavy chains were crossed with plants expressing light chains. The resulting plants expressed the assembled antibodies, see abstract.

Lomonosoff *et al.* disclose methods of preparing plant virus vectors containing foreign peptides, including antibodies, see column 2, lines 1-10. Infection of plants and/or plant cells with the nucleotide sequence is taught, see column 2, lines 49-63.

It would have been obvious to modify the method of Goodman with the teachings of Ma and Lomonosoff. One would have been motivated to incorporate the production of a monoclonal antibody into Goodman's method because Goodman teaches the production of antibodies in general, which in its broadest interpretation reads on monoclonals. One would have a reasonable expectation of success that a monoclonal antibody could be produced in the method of Goodman given the similarity of structure between polyclonal and monoclonal antibodies. One would have been motivated to infect plants (as opposed to only plant cells) in Goodman's method because Lomonosoff teaches that inoculation of whole plants is preferred when infecting with RNA virus vectors so that the multiplication stage is achieved prior to harvesting the resultant proteins, see column 2, lines 59-63. One would have had a reasonable expectation of success that infection of plants versus plant cells would result in antibodies being assembled in Goodman's method because the method of Lomonosoff teaches the production of antibodies using plant virus vectors.

Therefore, absent unexpected results, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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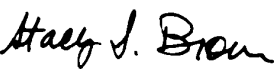
claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Stacy S. Brown
March 6, 2002


HANKYEL I. PARK, PH.D
PRIMARY EXAMINER